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EP 0299906 A WO 87/07494 A WO 80/02796 A

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INT CL[5] A61B

(54) **Ultrasound bone analyser**

(57) An ultrasound bone analyser with means for locating a patient's body member in relation to a pair of ultrasound transducers 14, 15.

To facilitate the obtaining of reliable attenuation measurements from both human and animal patients, respective silicone pads 24 are provided on opposed faces of the ultrasound transducers.

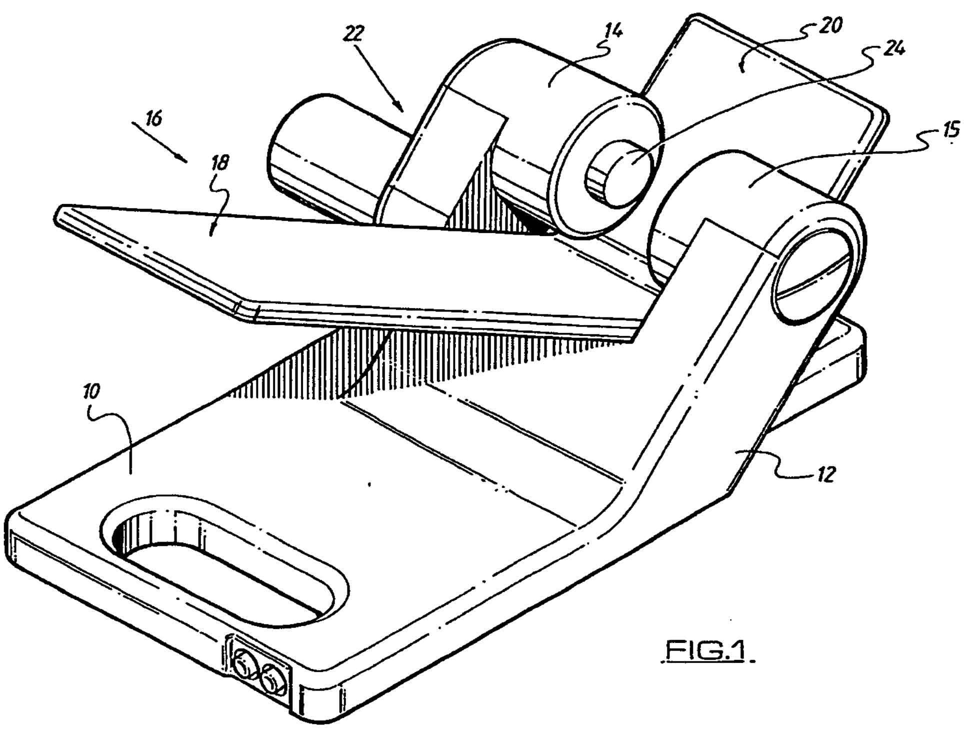

FIG.1

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1990.

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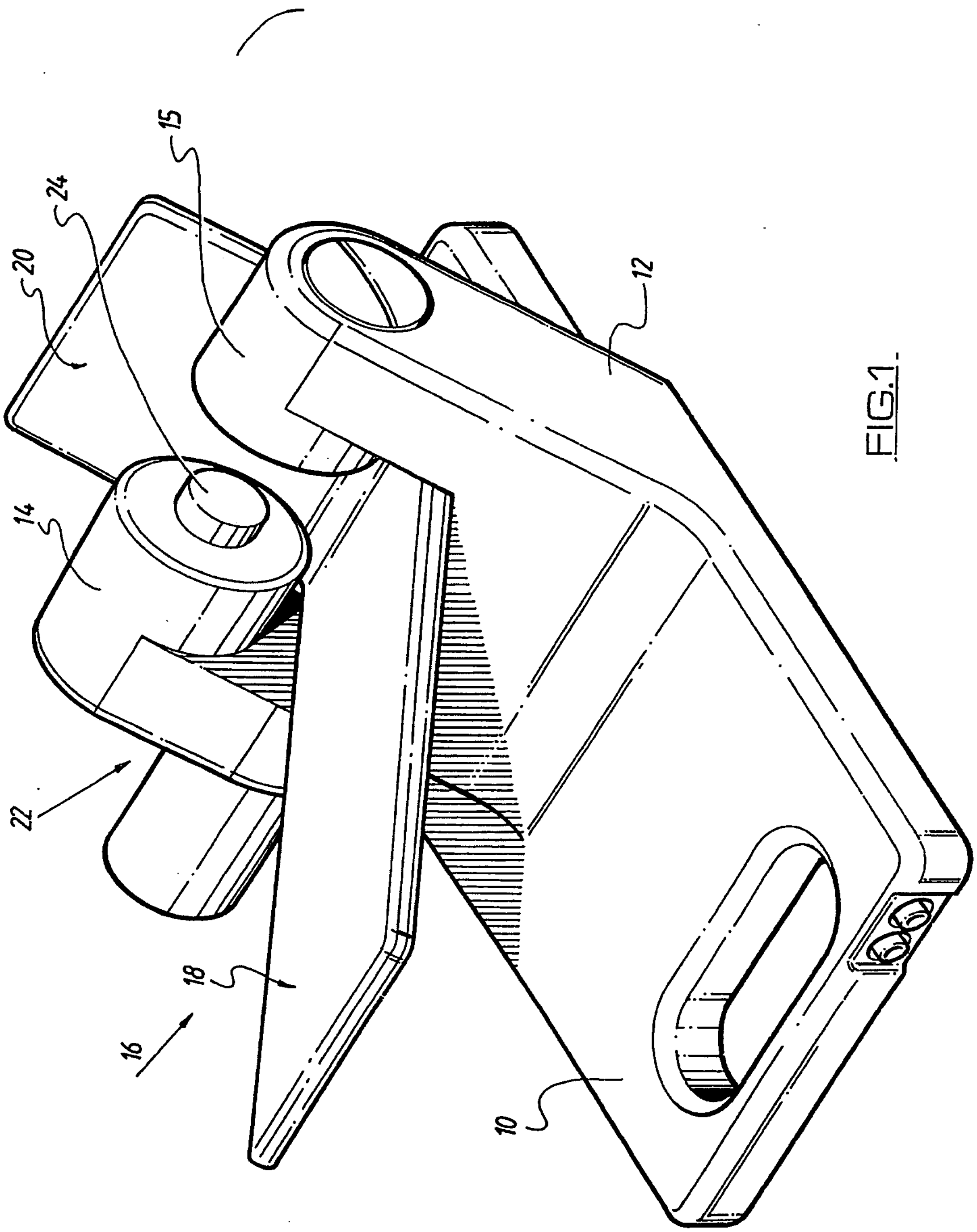

FIG.1

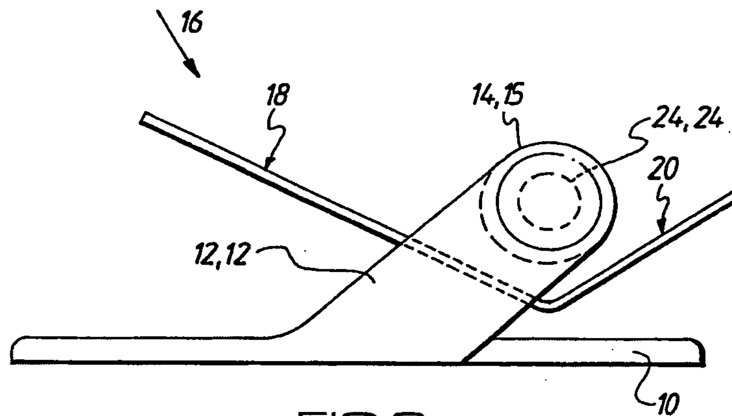

FIG.2

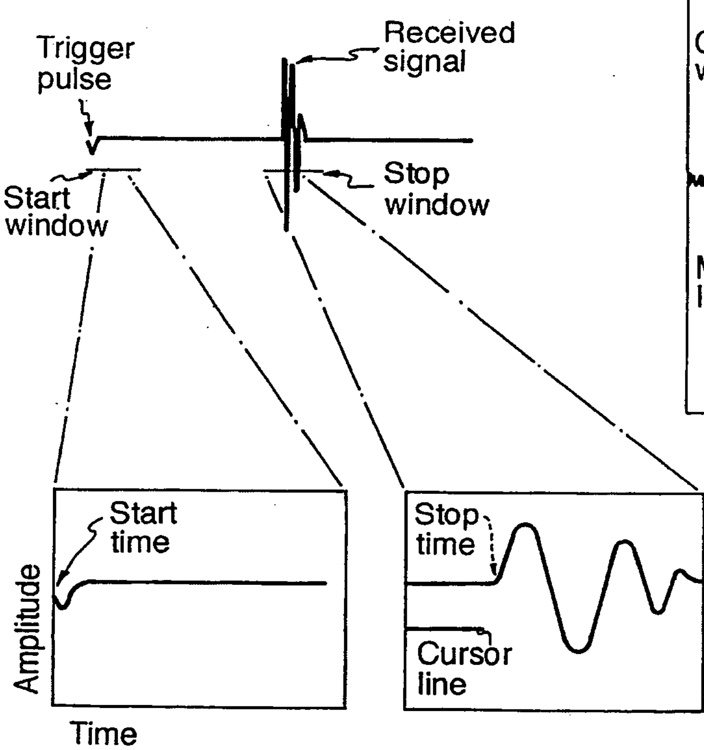

FIG.4

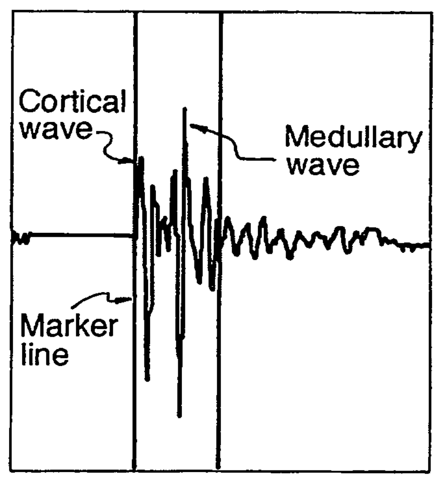

FIG.5

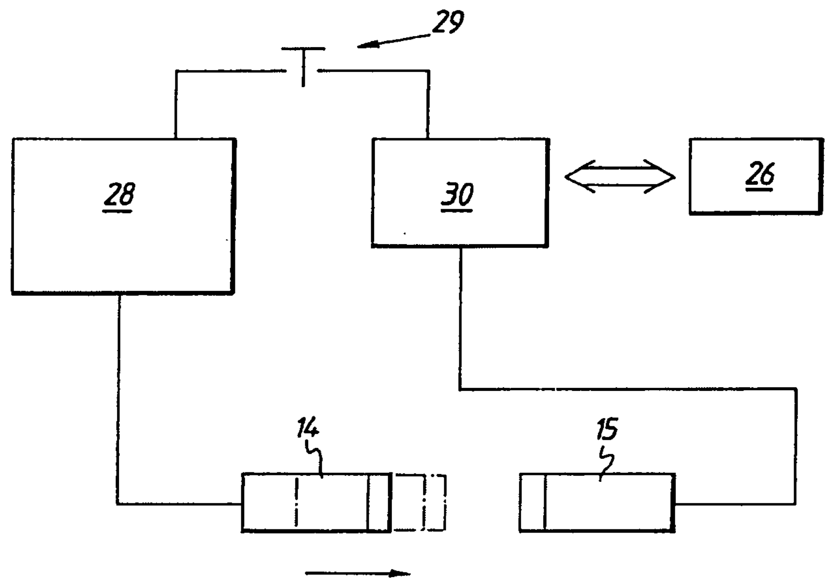

FIG.3

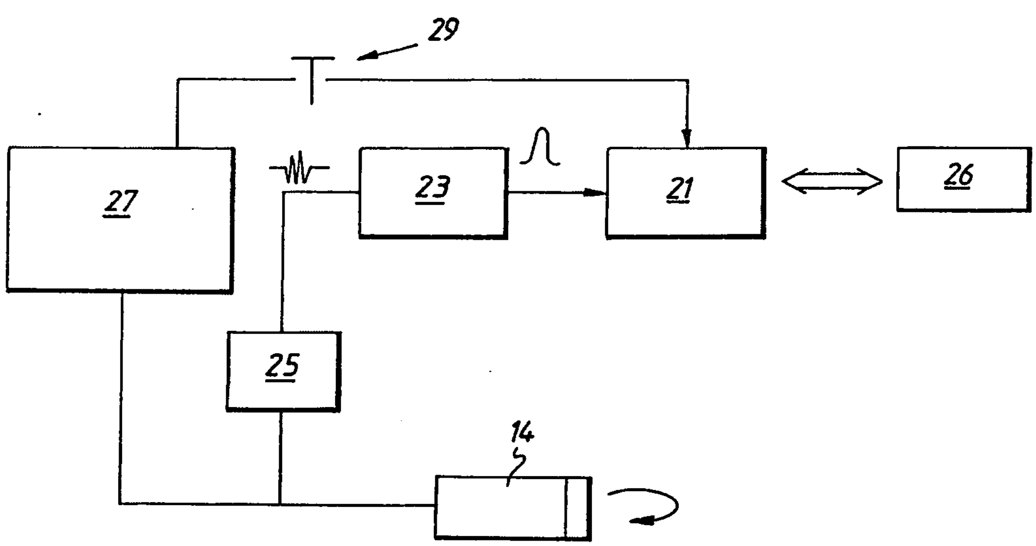

FIG.9

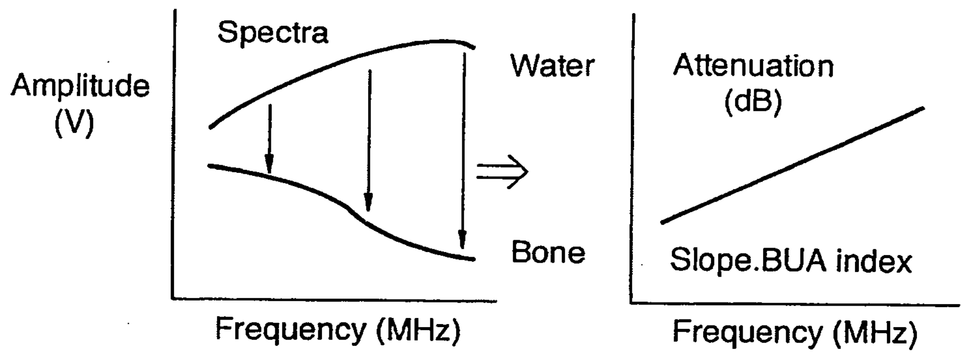

FIG.6

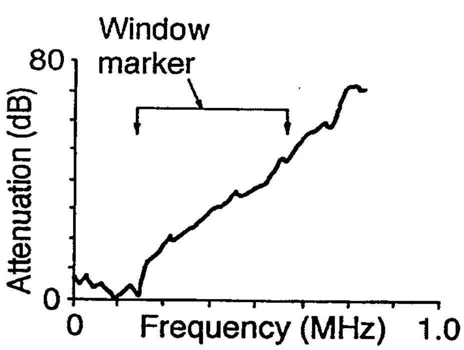

FIG.7

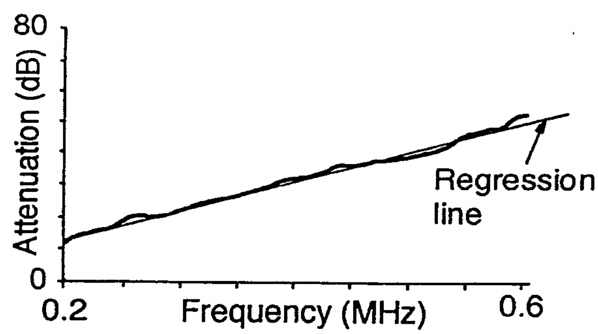

FIG.8

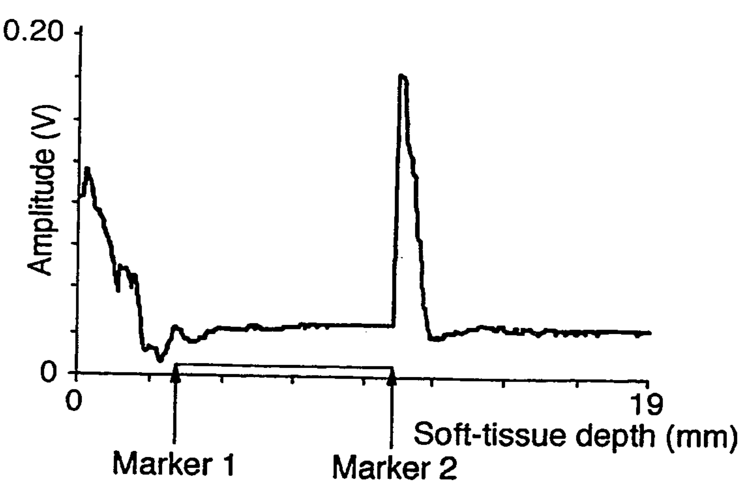

FIG.10

Ultrasound Bone Analyser

The invention relates to an ultrasound bone analyser mainly for use in the field of human medicine but also useful in the veterinary field.

There is an increasing need for a simple and easily usable means whereby individuals most at risk from bone fracture due to osteoporosis, that is to say loss of bone mineralisation, may be identified. Elderly persons are of course most at risk of this condition and, as the average life expectancy increases, the incidence of bone fractures due to osteoporosis in the general population is increasing also.

Various devices are known for measuring bone density. One of the most useful of these is one which uses ultrasound and which is therefore particularly advantageous in that it is basically non-invasive; the device measures ultrasonic attenuation as ultrasound is transmitted through a bath of water, first without and then with a patient's foot immersed in the water. The data derived from the test is a measure of bone ultrasound attenuation.

In the use of ultrasound, it has long been known that the velocity of the signal through a patient's

bone is a measure of the elasticity and density of the bone. However, it has more recently been found that by measuring broadband ultrasonic attenuation (BUA) there can be obtained data which is a measure of both the density and structure of cancellous bone. The data is expressed as the increase in ultrasonic attenuation with frequency in the range 200 kHz to 600 kHz.

The device just described is useful but has the one particular disadvantage of having a water bath which is something of a nuisance when used for testing the bones of human beings but which virtually rules out its use for testing the leg bones of thoroughbred race horses for example. The invention has for its object to provide an ultrasound bone analyser not prone to this disadvantage.

According to the invention, there is provided an ultrasound bone analyser including a main body and base member having a pair of upstanding arms at the upper ends of which are located respective ones of a pair of ultrasonic transducers in spaced opposed relation, one of said transducers being a fixed transducer and the other being a slideable transducer associated with a digital vernier gauge; respective silicone pads on the opposed faces of

the untrasound transducers, said pads being capable of being brought into contact with the patient's skin by adjustment of the slideable transducer; location means for a patient's body part to locate said body part with the ultrasonic transducers on opposite sides of an appropriate bone; and electrical spike generator means for providing a short broadband ultrasound pulse having frequencies spanning at least a range from 200 to 600 Kilohertz.

In order that the invention may be fully understood and readily carried into effect, the same will now be described, by way of example only, with reference to the accompanying drawings, of which:-

Figure 1 is a perspective view of an ultrasound bone analyser embodying the invention,

Figure 2 is a diagrammatic side view,

Figure 3 is a block diagram of electronic apparatus forming part of the analyser,

Figures 4 to 8 will be referred to in connection with the operation of the apparatus,

Figure 9 is a block diagram similar to Figure 3 but illustrating how the apparatus is used in pulse-echo mode, and

Figure 10 illustrates data displayed in the form of an A-scan when using the apparatus of Figure 9 to measure soft tissue thickness.

Referring now to Figures 1 and 2 of the drawings, the ultrasound bone analyser there illustrated has a main body and base member 10 upstanding from which are a pair of arms 12,12. Respective ones of a pair of ultrasonic transducers 14,15 are located at the upper ends of the pair of arms, as shown.

An angle member, generally indicated 16, is located, as shown, between the arms 12,12, the angle member including a sole plate 18 and a heel plate 20 arranged at an angle somewhat greater than a right angle to each other. The arrangement is such that when a patient's foot is located on the angle member, with the heel against the heel plate, the ultrasonic transducers are located on the opposite sides of the patient's ankle bone the characteristics of which are to be measured.

Referring now in particular to Figure 1 of the drawings, it will be seen that whereas the ultrasonic transducer 15 is a fixed transducer, the ultrasonic transducer 14 is a slideable transducer and is associated with a digital vernier gauge, generally indicated 22, which gives a reading of the spacing apart of the two transducers.

The fixed transducer 15 is an ultrasound receiving transducer and the slideable transducer 14 is an ultrasound transmitting transducer. The opposed faces of the two transducers are provided with respective silicone pads 24,24 which can be brought into contact with the patient's ankle by suitable adjustment of the slideable transducer.

Referring now to Figure 3, the electronic apparatus consists of an IBM PC-compatible portable computer 26 interfaced to a combined spike generator (transmitter) 28 and digital receiver 30 with a dedicated menu-driven software. A trigger 29 is provided to initiate an ultrasonic pulse. The transducers 14 and 15 are 1 MHz tranducers.

During operation, the screen initially displays a transmission ultrasonic signal. The amplitude and time sensitivity are controlled via the keyboard. For the calculation of velocity, the transit time is obtained via a digital timebase expansion method, see Figures 4 and 5. The 4096 collected data points are initially represented using only 256 horizontal screen pixels.

By selecting a region (window) of 256 data points and then displaying these on the screen, each pixel corresponds to an individual data point.

Figure 4 is a representation of the initial screen where 4096 data points are displayed on 256 screen pixels. By expanding a small region (window) of the screen, 256 data points may be displayed on the 256 screen pixels. Transmit time is measured from the beginning of the first window (trigger pulse) to the arrival of the chosen ultrasonic signal in a subsequent window. As shown in Figure 4, the user defines two windows, one containing the beginnings of the required transit time measurement, and a second containing the end of the transit time. Normally, the beginning of the transit time corresponds to the transmission of the ultrasonic pulse, that is, the initial data point when the trigger 29 is actuated. Once a time window has been selected, the user positions a screen marker via the keyboard at the beginning of the detected ultrasonic pulse of interest, as shown in Figure 5.

The transit time and corresponding velocity calculation may then be displayed. The precision of velocity measurement is typically 0.2% (based on 4 cm bone sample at 2500 ms^{-1} measured at 5us per division), since the resolution of time measurement is 1% of the timebase sensitivity and the resolution of transducer separation is 0.01 mm.

Attenuation data is calculated by subtracting the amplitude spectrum for a test sample from one obtained for a reference material, for example degassed water (see Figure 6). Comparison of the amplitude spectra provides the relationship between attenuation and ultrasonic frequency. A fast Fourier transform (FFT) algorithm is used to calculate the amplitude spectrum for a selected portion of the received signal. The resulting amplitude spectrum for the reference sample is stored on disc for subsequent comparison with the spectrum for the test sample.

Figure 7 shows a screen display of a typical attenuation trace. The software stores both the time domain (received signal) and frequency domain (amplitude spectrum) for the test sample on disc thus enabling additional data analysis if required.

In the attenuation trace shown in Figure 7, the position and width of a selected frequency window is shown to be indicated by a window marker, this being controlled via the keyboard. The start and stop frequencies are indicated and enable an additional spot frequency attenuation facility. The selected frequency window (typically 200 kHz to 600 kHz) is shown in Figure 8 to have been re-

plotted with regression analysis to provide an index of BUA.

Referring now to Figure 9, soft-tissue thickness is measured using a high resolution 5 MHz transducer, in pulse-echo mode, linked to a spike generator 27 and digital receiver 21, the data displayed in the form of an A-scan (see Figure 10). In Figure 9, the IBM PC-compatible portable computer 26 is shown to be interfaced to a spike generator and receiver, the receiver apparatus including a clipping circuit 25, a rectifying and smoothing circuit 23 and digital receiver 21. The depth range of the A-scan display may be varied, the indicated value of 19 m.m. being based on an average soft-tissue velocity of 1540 m s^{-1}. Tissue thickness d is calculated using $d = v.t$ where v is the user defined tissue velocity and t is the measured transit time. Screen cursors enable two independent compartment measurements to be performed. The user defines the two velocities, in most cases these being chosen to represent subcutaneous fat (1450 m s^{-1}) and muscle 1580 m s^{-1}) respectively. For small soft-tissue thicknesses, a stand-off may be incorporated in which case the first marker is positioned over the echo corresponding to the stand-off, and the second

marker positioned over the soft-tissue echo of interest. Soft-tissue thickness may be recorded for both medial and lateral sides. Thus, the transducer separation and transit time may be corrected to allow a velocity to be measured in bone alone. The corrected bone thickness is incorporated into the BUA index, presented as dB MHz^{-1} cm^{-1}, a volumetric parameter. It will be understood that the transit time of the silicone pads 24,24 is automatically normalised within the system algorithm.

Thus there is provided an ultrasound bone analyser which is a portable, easily used and non-invasive means of obtaining ultrasonic velocity and attenuation measurements on both cortical and cancellous bone. The device can be used with the transducers in direct contact with the subject and is therefore ideal for screening elderly human patients for those at risk of bone fracture due to osteoporosis. However, the fact that the device does not include a water bath, together with the fact that the digitised time domain data is collected within a very short space of time, for example one second, makes it ideal for use in the veterinary field, that is to say for screening thoroughbred race horses to identify those most at

risk from leg fractures. The use of silicone pads on the opposed faces of the two transducers has been found to facilitate the obtaining of reliable attenuation measurements from both human and animal patients.

Various modifications may be made. For example, in the operation of the apparatus transit time measurement may be performed automatically via the software. A fixed frequency range may be selected via the software. Furthermore, it is not essential for the apparatus to be adapted for the reception of a patient's foot. Any other suitable body part could be located in the apparatus to bring the ultrasonic transducers into position on opposite sides of an appropriate bone.

The apparatus may be modified for veterinary use, for example so that it can receive or be placed around a horse's leg.

CLAIMS:

1. An ultrasound bone analyser including a main body and base member having a pair of upstanding arms at the upper ends of which are located respective ones of a pair of ultrasonic transducers in spaced opposed relation, one of said transducers being a fixed transducer and the other being a slideable transducer associated with a digital vernier gauge; respective silicone pads on the opposed faces of the ultrasound transducers, said pads being capable of being brought into contact with the patient's skin by adjustment of the slideable transducer; location means for a patient's body part to locate said body part with the ultrasonic transducers on opposite sides of an appropriate bone; and electrical spike generator means for providing a broadband ultrasound pulse having frequencies spanning at least a range from 200 to 600 Kilohertz.

2. An ultrasound bone analyser constructed, arranged and adapted to be used substantially as hereinbefore described with reference to and as illustrated by the accompanying drawings.

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Patents Act 1977
Examiner's report to the Comptroller under Section 17 (The Search Report)

Application number
GB 9112996.5

Relevant Technical fields

(i) UK Cl (Edition K) G1G GEEH, GPB, GPN

(ii) Int Cl (Edition 5) A61B

Databases (see over)

(i) UK Patent Office

(ii)

Search Examiner
A J OLDERSHAW

Date of Search
28 SEPTEMBER 1992

Documents considered relevant following a search in respect of claims 1, 2

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X	EP 0299906 (UNIVERSITY OF MELBOURNE) See particularly Figure 1A; page 5 lines 15-20	1
X	WO 87/07494 (M.I.T) See particularly Figure 3; page 21 lines 6-18; page 27 line 12 - page 28 line 6	1
X	WO 80/02796 (PRATT) See particularly Figure 2	1

SF2(p)

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Category	Identity of document and relevant passages	Relevant to claim(s)

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

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P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family, corresponding document.

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).

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